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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,549	10/18/2004	Takahide Ohishi	Q102803	9316

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EXAMINER	
PETERSEN, CLARK D	
ART UNIT	**PAPER NUMBER**
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,549	OHISHI ET AL.	
	Examiner	Art Unit	
	Clark D. Petersen	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-10 and 13-17* is/are pending in the application.

4a) Of the above claim(s) *8-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendment, filed 16 August 2007, in which claim 12 was canceled, claims 7, 9, and 13 were amended, and new claims 14-17 were presented. Claims 8-10 stand withdrawn **without** traverse. It is suggested that the non-elected claims be canceled in response to this Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

All objections and rejections not repeated in the instant Action have been withdrawn due to Applicant's response to the previous Action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7 and 13-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19 and 21-25 of copending Application No. 10/975367.

This is a new rejection.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a method using a nucleotide vector comprising the same sequences; instant SEQ ID NO:2 is identical to SEQ ID NO:2 of 10/975367 and instant SEQ ID NO:4 is identical to SEQ ID NO:16 of 10/975367. The claims are directed to using identical polypeptides expressed from DNA vectors transfected into cells in method increasing insulin production, insulin content, and insulin-stimulatory signaling in the cells.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7, 12, 13, and 16 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

This rejection was previously presented in the Office Action mailed 16 May 2007 and is maintained for reasons of record and as set forth below.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide reasonable written description for polypeptides of SEQ ID NO: 2 or 4 in which 1 to 15 amino acids are deleted, substituted, or inserted, and additionally does not provide support for a method wherein the polypeptide has 80% or greater homology. For the same reason, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, no characteristics are provided to support the invention of claims 7 and 12-13.

Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the

claimed genus of any polypeptide with 80% homology to, or 1 to 15 amino acid substitutions in, SEQ ID NO: 2 or NO:4.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed sequence or substitutions of the encompassed genus, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that a claim is part of the invention and reference to a potential method of practicing it.

There is no mention in the instant specification of which amino acids one of ordinary skill in the art would substitute and maintain a functional polypeptide that would provide a useful tool in an assay for insulin content enhancement. For example Guo et al (PNAS, 22 June 2004) teach that single random amino acid changes can abrogate enzyme function, and that the probability of a random change compromising function is about 34% for each change (see Results and Discussion, pp. 9205, col. 2, to 9206, col. 2, for example). It is well known in the art that once the functional domains of proteins are mapped, site directed mutagenesis can be performed, such that certain amino acids

can be substituted that completely change the functional character of the enzyme, whereas substitutions in other locations can have no effect. Applicants have offered no specificity in their instant specification that supports a "blanket" claim that any protein within 80% homology, or containing 1 to 15 substitutions of SEQ ID NO:2 or :4 is suitable in the instant invention. There is no indication as to which amino acid substitutions, insertions, or deletions are possible which maintain an ability to "exhibit activity of promoting insulin production by activation".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7 and 13-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al (US 7,108,991, issued 19 September 2006, which claims priority to provisional application 60/141,448, filed 29 June 1999).

This is a new rejection. Chen et al (7,108,991) is drawn from the IDS filed by Applicant 16 August 2007.

Chen et al teach a method of using a G protein-coupled receptor called RUP3 in an assay for identifying compounds that modulate insulin production. RUP3 (also

identified in the patent of Chen et al as SEQ ID NO:8) is identifical to instant SEQ ID NO:2. Specifically, the RUP3 DNA is inserted into a DNA vector which is transfected into cells; the cells are then contacted with an agonist or antagonist that inhibits or stimulates insulin production (see Claims 1-11, for example). The step of "confirming" recited in instant claim 13 is a step of repeating; one would expect the same results from the steps recited in Chen et al regardless of the number of times the assay is performed.

Therefore the teachings of Chen et al are deemed to anticipate instant claims 7 and 13-17.

Response to arguments - 35 USC § 112

Applicants traverse the rejection of Claims 7 and 12-13 under 35 USC 112 first paragraph in the Office Action mailed 16 May 2007 as lacking written description.

Applicants argue that SEQ ID NO:2 and SEQ ID NO:4 share over 80% homology. Applicants also argue that by aligning the sequences with those of other mammals such as mice, one can identify which residues are functionally important and those that are irrelevant and thus could be substituted without affecting the activation of the polypeptide in its role in insulin production.

Applicant's arguments have been fully considered but are not deemed persuasive. First, Applicant is correct that the SEQ ID NO:2 and SEQ ID NO:4 share over 80% sequence identity, so Examiner's assertion that there are no examples of such a polypeptide is not totally correct. It is also correct that those of ordinary skill in

the art typically use sequence alignments such as that provided with Applicant's Remarks to guide them in determining which residues are functionally important. However Applicant claims *the entire genus* of polypeptides with any 1 to 15 residues varying from those of SEQ ID NO:2 and 4 as well as the entire genus of polypeptides with 80% homology to either sequence. Furthermore, there the algorithms cited in the Remarks are far from perfect in predicting the exact functional effect of substituting particular resides, and sequence alignments between species are also not always precise. Applicant must provide specific examples of polypeptides that can activate insulin production.

Applicants traverse the rejection of Claims 7 and 12-13 under 35 USC 112 first paragraph in the Office Action mailed 16 May 2007 as lacking essential steps, and as being indefinite for using the term "activation".

Based on Applicant's amendment and arguments, that rejection is withdrawn.

Response to arguments - 35 USC § 102

Applicants traverse the rejection of claims 7 and 12-13 under 35 USC 102(b) in the Office Action mailed 16 May 2007 as being anticipated by Fehmann et al. Based on Applicant's amendment to instant Claim 7, that rejection is withdrawn.

Response to arguments - 35 USC § 103

Applicants traverse the rejection of claims 7 and 12-13 under 35 USC 103(a) in the Office Action mailed 16 May 2007 as being unpatentable over Bonini et al (US 6,221,660). Based on Applicant's arguments, that rejection is withdrawn.

Conclusion

Because the grounds for new rejection are based on Applicant's IDS submitted after the non-final rejection was mailed, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action.. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571)272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDP
10/23/2007

/Jon P Weber/
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